Pharmaceutical monitoring and evaluation

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Topics

- Concepts on pharmaceutical assessment/monitoring
- The WHO process on assessing and monitoring pharmaceutical situation
- Undertaking survey, sampling and concepts on indicators

Pharmaceutical monitoring/ evaluation

Monitoring

- **Review of the progress re completion, allows for corrective action, focus on inputs and outputs**
- **Common methods**
  - **Supervisory visits**
  - **Routine reporting of selected data**
  - **Sentinel sites for more detailed reporting/ intensive monitoring**
  - **Special studies for specific additional information**

Evaluation

- **Part of overall pharmaceutical assessment, progress on meeting objectives**
- **Types of evaluations**
  - **Needs assessment (situation analysis,**
  - **Formative evaluation (midterm review)**
  - **Summative evaluation (final evaluation)**
  - **Field surveys using standard pharmaceutical indicators & ongoing monitoring system, document review**

Strategies developed in parallel for comprehensive unified strategy

Who can use the results from assessment and monitoring?

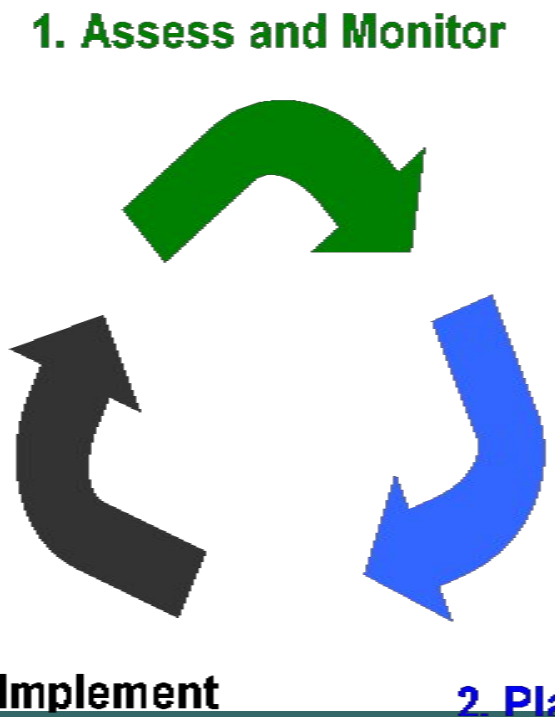
- Countries - focus action, prioritize, measure achievement
- National policy-makers
  - synchronise policies
  - data and information to donors and other governmental agencies
- International agencies
  - to assess the structure and capability of countries, assess the progress, accomplishment and impact of aid
- Professional groups, NGOs and academia
  - to focus advocacy activities and information campaigns
- Health facilities to be aware of institutional problems & improve situations

WHO Evidence-Based Planning and Interventions

Guiding Country Works in Medicines

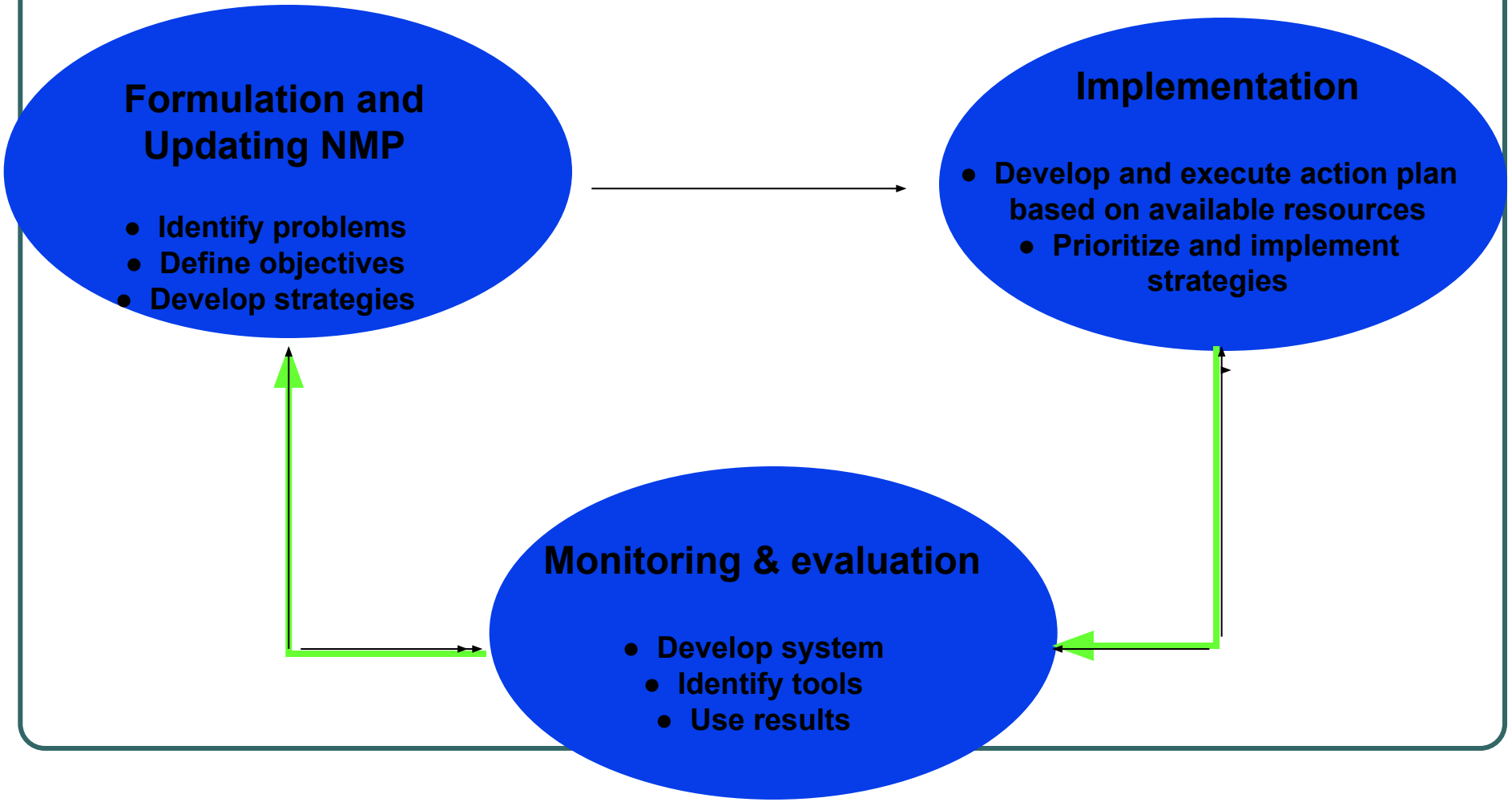
Indicator-based tools to evaluate structures, processes, outcomes of in countries

Support implementation of activities and advise in the execution of work plans



Develop implementation plans and identify strategies & interventions based on data/information on: **availability, affordability, pricing, drug use and regulatory profile, TRIPS, drug management situation.**

National Medicines policy process

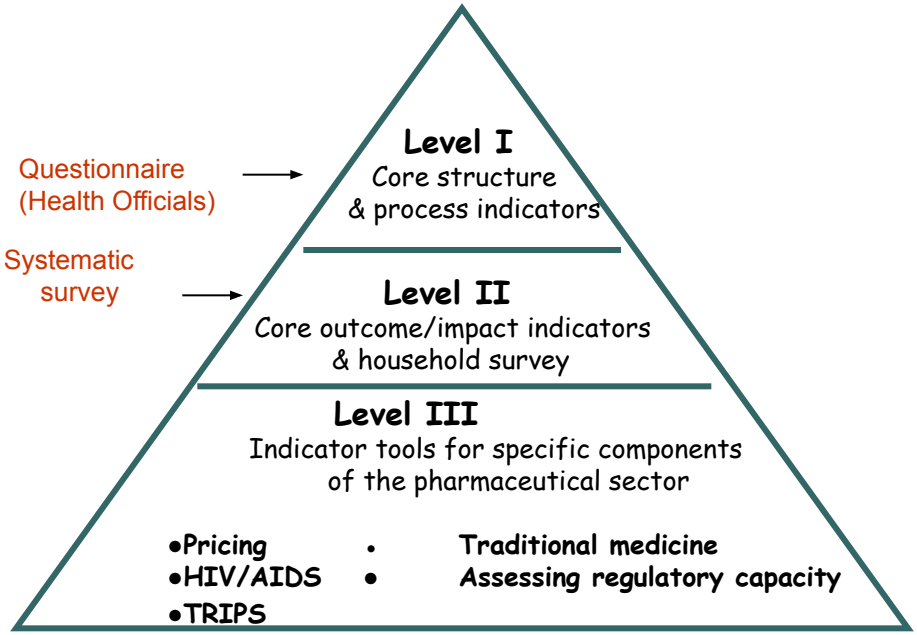


WHO hierarchical approach to monitoring and assessing pharmaceutical situations

Level I
- Questionnaire/rapid assessment/checklist
- Arrays achievement & weaknessess, illustrate sectoral approaches

Level II
- Comprehensive monitoring of pharmaceutical strategy outcome and impact
- Measures attainment of objectives

Level III
- More detailed indicators for monitoring and evaluating specific areas/components



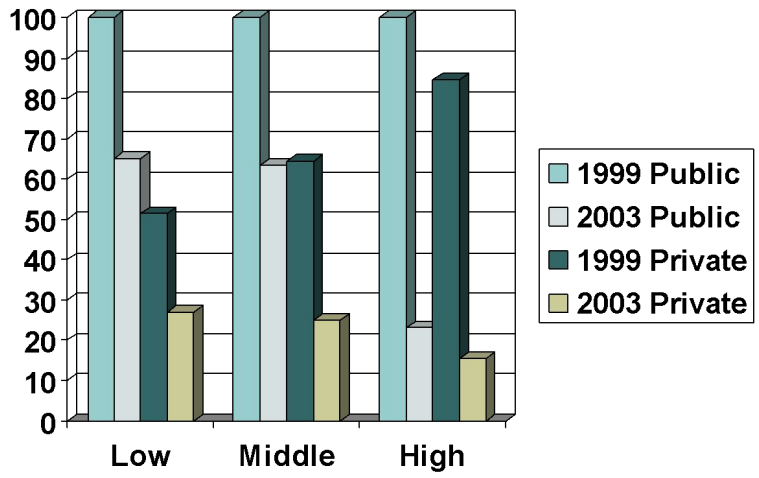
Level I indicators: structure and process indicators

- **Regular survey questionnaire**
  - Inexpensive process to get information across countries
  - Can be done repeatedly/regular period
  - Automated questionnaire and data encoding processing
- Contents
  - National Medicines Policy
  - Regulatory system (marketing authorization, licensing, regulatory inspection, etc)
  - Medicines supply system, medicines financing, production and trade
  - Rational use of drugs

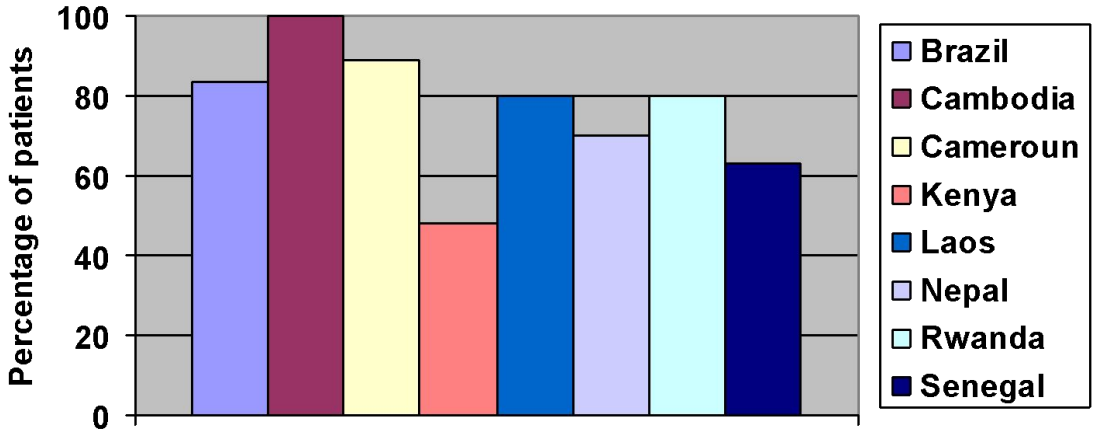
Level II- facility outcome and impactindicators: *WHO Operational Package for Monitoring and Assessing County Pharmaceutical Situations"*

- Sytematic survey
- Indicators
  - on availability, stock out, record keeping and expiry of key drugs
  - conservation conditions and handling of medicines
  - affordability (child and adult moderate pneumonia and option for other disease condition
  - drug prescribing, dispensing, patient knowledge
- practical/operational system of managing a systematic survey and resources
- 17 survey forms-public health facilities, public pharmacy/dispensary, private pharmacy, warehouses
- manual calculation and automated system for descriptive analysis

Generic prescribing and substitution regulations in 1999 and 2003



Generic prescribing at public sector



Measuring access to essential medicines (Household Survey)

- Level I and Level II- facility surveys do not measure access from the patient/consumer perspective.
- **Only** household surveys can provide population-based information about how pharmaceutical policies affect the well-being of individuals.

Importance of household survey

- Household situations
  - How they access their medicines, where they get them
  - How much they pay
- Identify access and affordability in relation to socio economic indicators, barriers
- Examine use of medicines (acute and chronic diseases)
- Perceptions on access, use and quality; handling of medicines

Indicators: (few examples)

Affordability

- Average household medicine expenditures as % of total/non-food/health expenditures
- Average household medicine expenditures for a reported illness (acute, chronic, by illness)
- % of households with at least partial medicine insurance coverage

Mixed Indicators of Access (availability)

- Percent of households reporting a serious acute illness who sought care outside but did not take any medicine.
- Percent of households who do not have at home a medicine prescribed to a chronically ill person.

Indicators: (few examples)

Rational Use of Medicines

- Percent of antibiotics kept for future use
- Percent of household medicines with adequate label/ adequate primary packaging

Perception of quality

- Percent of respondents who agree that quality of services at their public health care facility is good / quality of services by private provider is good
- Percent of respondents who agree that brand name medicines are better than generics/ imported medicines are of better quality than locally manufactured medicines.

Current issues on household survey process

- Challenge to use population based data to policy evaluation, development and planning
- Segregation by socio economic profile
- No basic guideline standard???on household survey
  - What is a household / who is a household member
  - Sampling
  - Recall periods- (number of days, self report, caregivers)
  - Type of survey (general population, disease based survey)

Level III Indicators

- Systematic survey and monitoring
  - Drug price survey and monitoring
  - WHO/INRUD RDU indicators
- Rapid assessment
  - Global survey on Paediatrics medicines
  - Questionnaire on public sector medicines procurement and supply management systems in countries
  - Assessment of regulatory capacity

Sampling issues for systematic survey

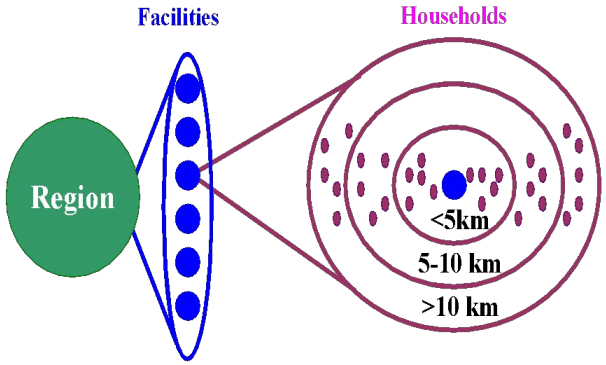
- Follow specific procedures to minimize selection bias and is representative of the reference population
- A balance between what is desirable and what is feasible- smallest one with a degree of precision

Sampling Recommendation for Level II facility survey

- Sampling (stratification, random)
  - 5 regions/districts
    - 1 should be among the lowest income generating areas
    - 1 should be the largest or capital city
    - 3 others should be randomly selected
  - 30 facilities each
  - 30 cases per facility
- Systematic sampling
- Non probability / purposive/ quota sampling

The household survey sampling scheme (non probability, convenient

- 5 regions in the country
- From each region select 6 public health facilities (30 reference public health facilities)
- In each of reference facility, select 30 households (900 households)

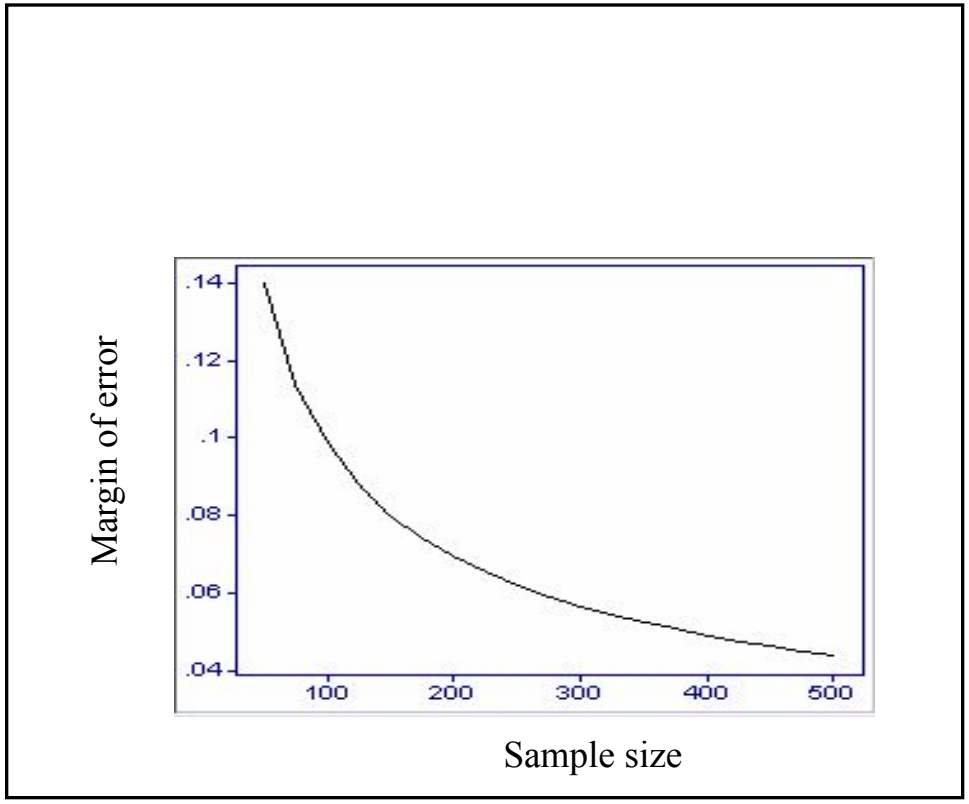


Is the sampling frame valid? *(clustering in drug supply or drug use data)*

- Geographic Characteristics
  - Administration and drug supply system
  - Epidemiologic or socio-economic differences
- Health Facility Characteristics
  - Differences in management
  - Peer norms and collective habits
- Provider Characteristics
  - Training, knowledge, clinical experience
  - Economic incentives
  - Industry pressure

Result: Effective sample size is reduced

Error due to simple random sampling



Who can be trained to do the survey?

- Physicians, nurses, pharmacists or paramedical staff
- Health ministry/department staff and temporary employees (health related background and experience)
- data collectors from different parts of the country (language differences)

Preparing and implementing systematic survey

- ***Administrative preparation:***
  - **Coordinating with WHO, ministry/department of health, public health facilities, private drug outlets, warehouses**
  - **Making logistic arrangements and budget allocations**
- ***Technical requirements:***
  - **Tailoring the tool-specific items of the survey forms, e.g. key basket of medicines, treatment guidelines, etc.**
  - **Training data collectors to carry out the survey and use the survey and summary forms**
  - **Analyzing and computing the data**
  - **Preparing a report and using result**

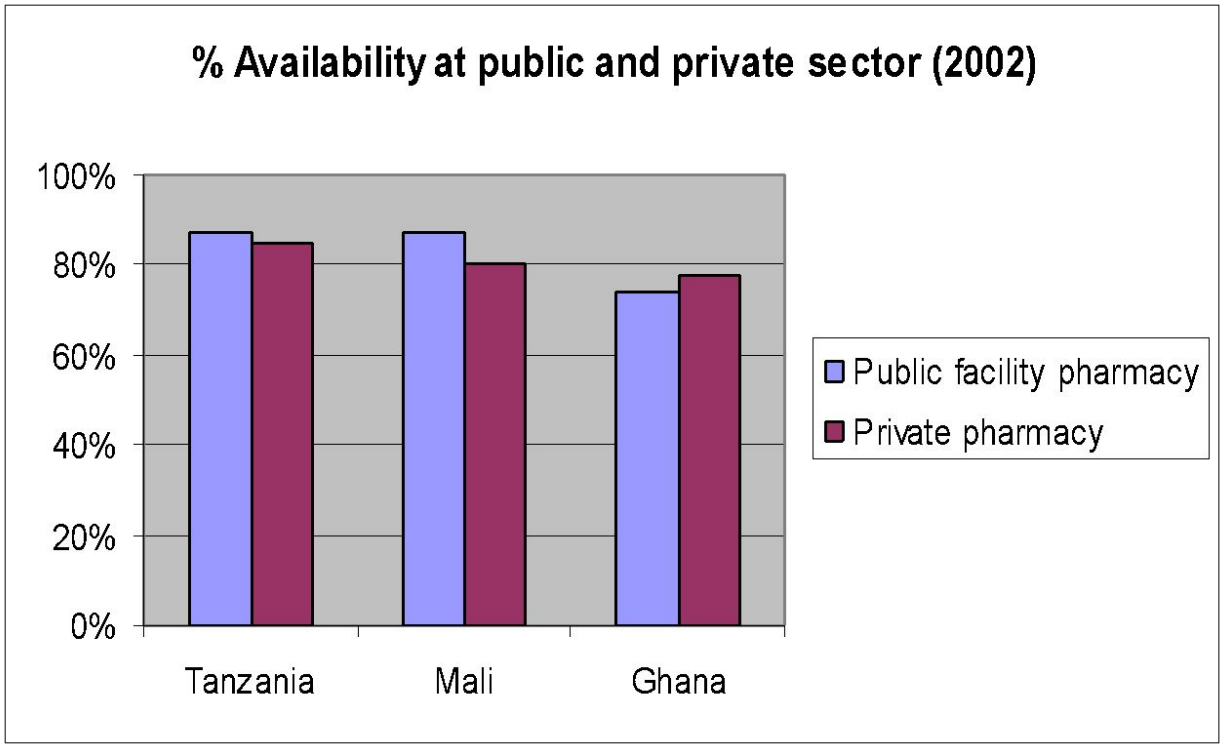
Pharmaceutical indicators

- Variables that measure situations and change
- Numerical (numbers, percentage, or averages)
- Binomials (yes" and "no)"
- Linked to an important input, process, or outcome
- Well-established indicators can be adapted/ modified to reflect the realities
- Field test

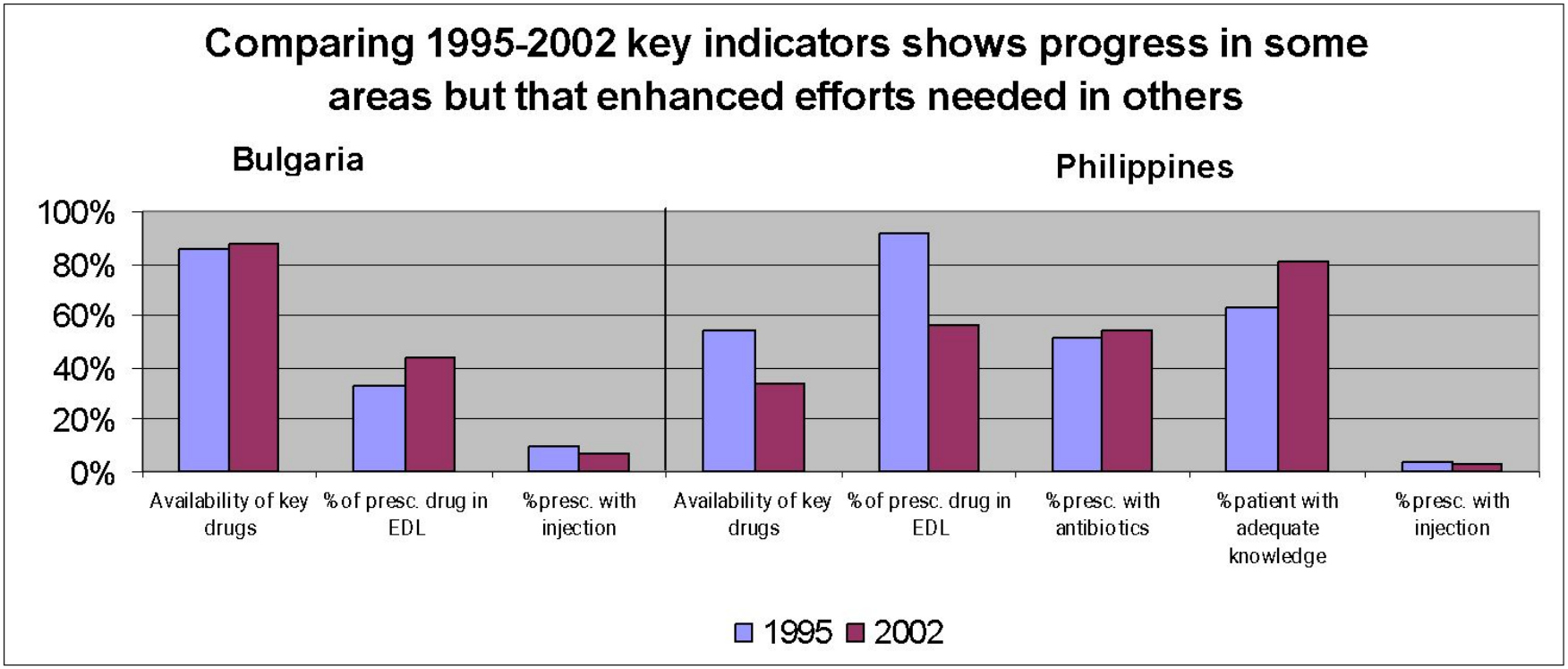
Why is it important to use indicators?

- Standard indicators facilitates:
  - **comparing** the performance of facilities, districts, urban vs rural, private & public sector, overall situations in countries
  - seeing **trends** over time
  - setting **target**

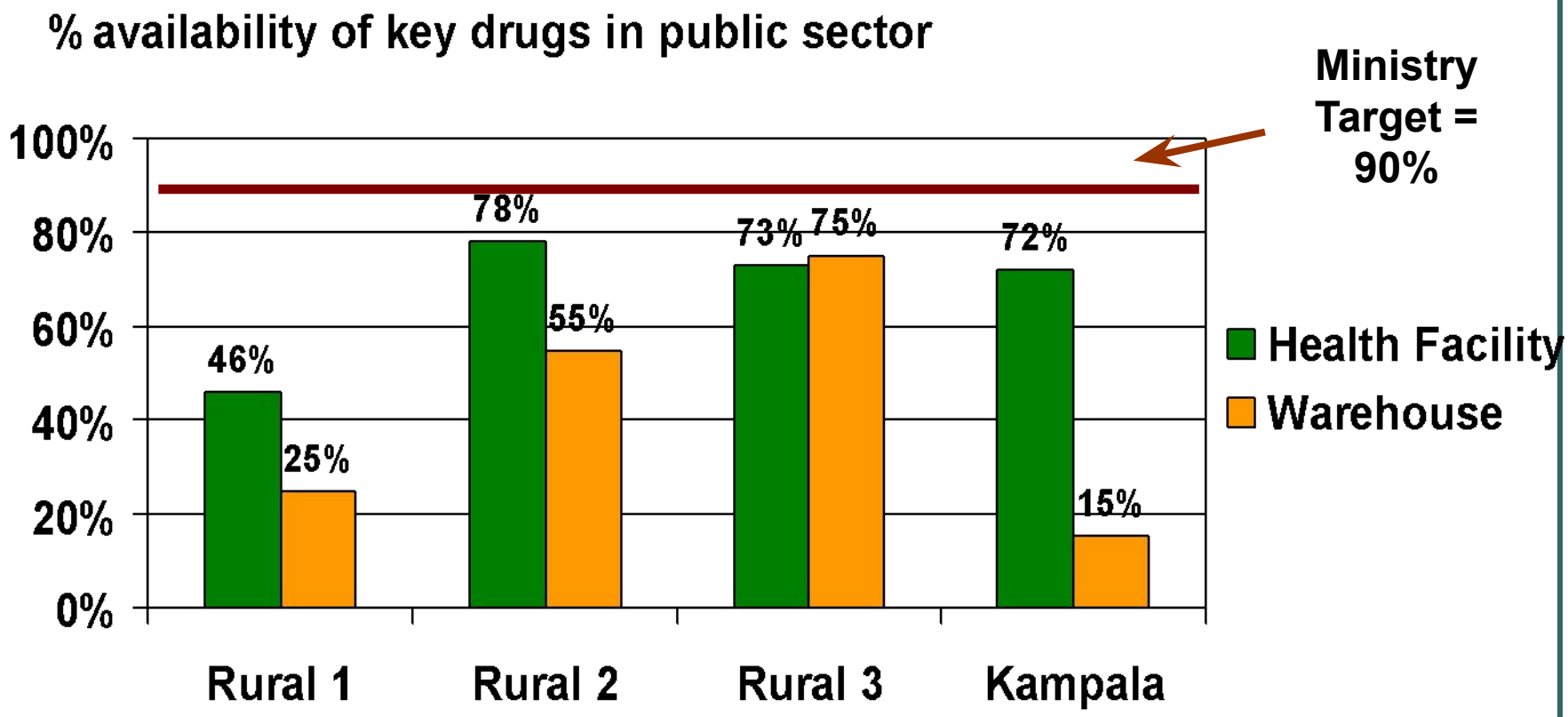
Indicator allows comparison



Monitoring if there is progress or none



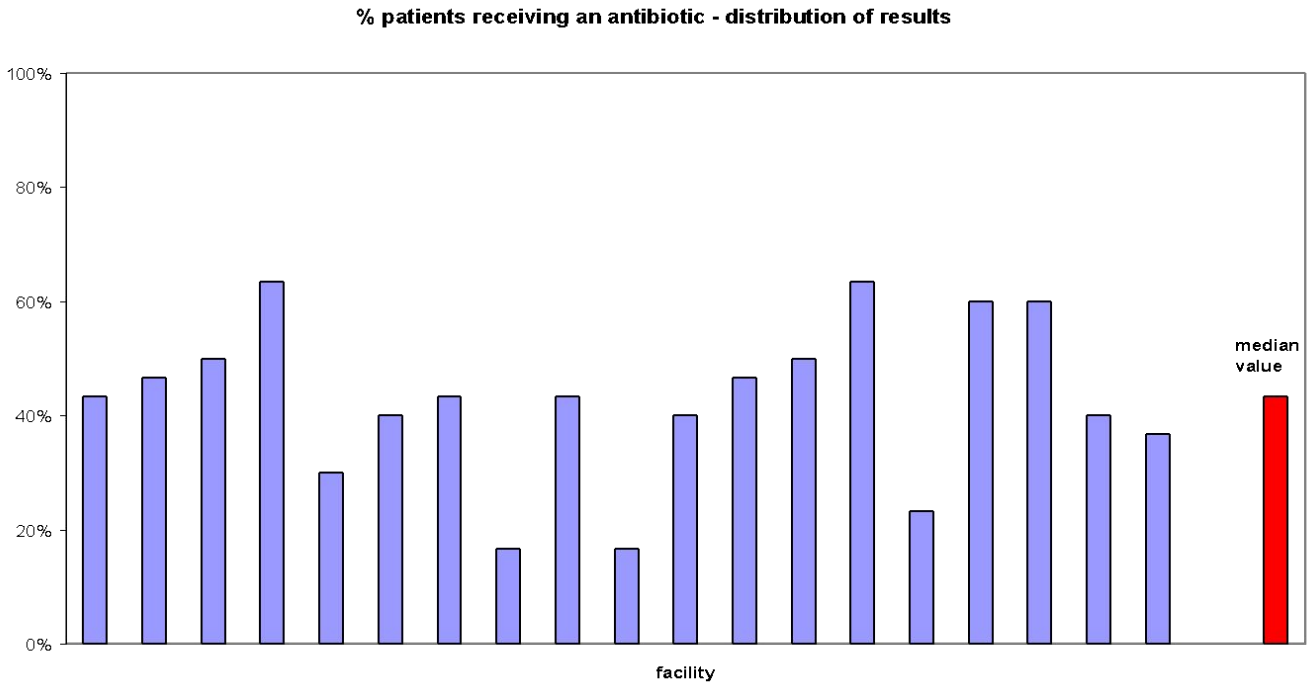
Setting target



Indicator measure: group norm

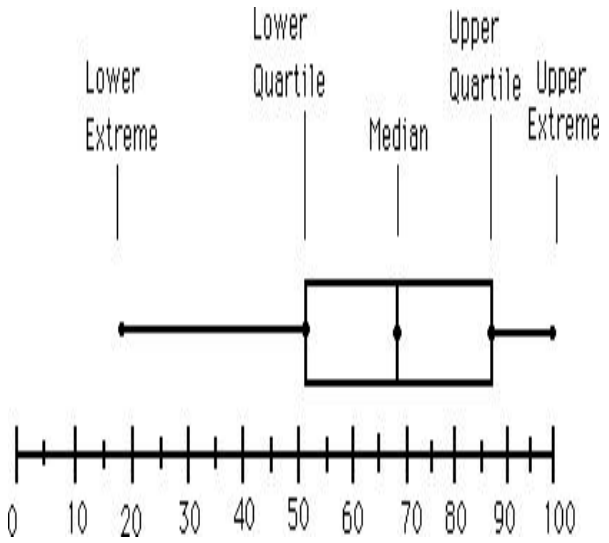
- Easy for region/facilities to relate to peers
- Norms may be wrong

Example: % antibiotic prescribing (logical value is <30%)



Summarizing indicator measures

- Percentage: yes or no over total
- Measures of central tendency
  - Mean: average value, sensitive to outliers, weighed toward skewed value, best summary of normally distributed values
  - Median: middle value, resistant to outliers, good summary of any distribution
    - Equivalent if data are normally distributed
- Measure of variation
  - 25th and 75th percentiles: boundaries of middle half of values, good summary of the overall spread of values, better summary of skewed data



Indicator measure: Ideal/logical values

Logical value exist for some

- Logical value (100%-adequate labelling, meds dispensed, adherence to STG, availability of medicines, generic, adequacy of storage; 0 days of stock out,)

Others need further studies

- affordability (economic profile)
- Antibiotic use and injection, meds prescribes are more complex- are (<30, <20 and < 2 and can be controversial)
  - **Optimal value largely depend on disease pattern, policies and treatment G/L and vary from country to country**
  - **These values can be calculated empirically**

Connecting Survey Results and Interventions

1. Average number of drugs per encounter

High number of drugs per encounter

Are there shortages of therapeutically correct drugs? Do prescribers lack therapeutic training or appropriate diagnostic equipment? How secure are prescribers in their ability to diagnose and treat the common illnesses? How strongly do prescribers feel that patient demand influences their practice, and do observations of clinical encounters support this? Are there financial incentives to encourage polypharmacy?

Low number of drugs per encounter

Are there absolute constraints in the drug supply system such that very few drugs tend to be available? Are there administrative regulations that limit the number of drugs that can be prescribed? Do prescribers have appropriate training in therapeutics? Is there significant drug "leakage" from the system?

The way forward on country monitoring

- Evidence through systematic but feasible data collection process is necessary in policy making and activity implementation. This should include population based information
- Should demonstrate that in the long run regular monitoring and evaluation is not difficult and can be done in a cost efficient manner
- Portion of country support budget and project grants should be allotted to monitoring and evaluation using indicators
- Timely report and information/data sharing


THANK YOU